



California Medical Device Recall Information



Recall Name

Siemens Healthcare Diagnostics Recalls Rapid Gram Negative Combo Panels Due to Incorrect Test Results

Recall Date	Product Description	Recalling Firm	Recall Reason
10/17/14	<ul style="list-style-type: none">Rapid Neg BP Combo Panel Type 3 <i>Catalog #B1017-117</i>Rapid Neg Urine Combo Panel Type 1 <i>Catalog #B1017-167</i>	Siemens Healthcare Diagnostics West Sacramento, CA	<i>Incorrect test results may occur for the following antibiotics: Aztreonam, Cefotaxime, Ceftazidime, and Ceftriaxone.</i> <i>The test may report certain bacteria as sensitive to one of these antibiotics when they are actually resistant.</i>

Recall Class	Product Identification	Distribution	Affected Dates		
I	<p>Rapid Neg BP Combo Panel Type 3 Lots:</p> <ul style="list-style-type: none">• 2014-12-10• 2015-02-27• 2015-06-23 <p>Rapid Neg Urine Combo Panel Type 1 Lots:</p> <table><tr><td><ul style="list-style-type: none">• 2014-11-01• 2015-01-03• 2015-02-14• 2015-03-21</td><td><ul style="list-style-type: none">• 2015-05-20• 2015-06-18• 2015-07-18• 2015-08-11</td></tr></table>	<ul style="list-style-type: none">• 2014-11-01• 2015-01-03• 2015-02-14• 2015-03-21	<ul style="list-style-type: none">• 2015-05-20• 2015-06-18• 2015-07-18• 2015-08-11	CA, nationwide	<p>Manufacturing Dates:</p> <p>November 1, 2013 – August 11, 2014</p> <p>Distribution Dates:</p> <p>December 2013 – September 2014</p>
<ul style="list-style-type: none">• 2014-11-01• 2015-01-03• 2015-02-14• 2015-03-21	<ul style="list-style-type: none">• 2015-05-20• 2015-06-18• 2015-07-18• 2015-08-11				

FOR ADDITIONAL INFORMATION, PLEASE VISIT:

<http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm425249.htm>